

are preferably integrated for each acquired data point and the ratio of these two values (current relative to applied voltage) can then be compared against threshold values; these threshold values may be assay-dependent. Results with very low relative current are preferably flagged as probable open circuit conditions while results with very high relative current are preferably flagged as probable short circuits. This information can be stored in relational form for later review/consideration. Alternatively, if either condition is detected, the results can be considered invalid and concentrations for those measurements not reported/computed.

[0284] In the case where a voltage following quality assessment is to be employed, each point of the acquired voltage waveform is preferably compared to its corresponding point in a sampled output waveform. Preferably, a predetermined fixed voltage following limit value is defined for the instrument (i.e., cartridge reader/cartridge) and if any pair of points differs by more than that predetermined value (i.e., $|v(t)_{\text{defined}} - v(t)_{\text{measured}}| < \text{voltage following limit}$), the results are preferably flagged or considered invalid. If the results are flagged, this information can be stored in relational form for later review/consideration. If the results are considered invalid, the computed results for those data points are preferably not reported/computed.

[0285] Finalization of the cartridge read operation can occur once all of the requisite measurements have been made and all the requisite fluid processing has occurred (e.g., once the final measurements have been made, route all remaining fluid(s) within the channels and/or read chamber(s) into the waste chamber(s)) the cartridge may be ejected from the reader. The cartridge ejection operation preferably occurs in reverse of the operation used to draw the cartridge within the reader. Specifically, the cartridge reader controller ensures that the pump vent is open and that all other valves are closed. Confirmation that the pump is stopped and all electrode contacts are tri-stated is obtained and, if a cartridge heater is present and employed, deactivate the cartridge heater. The cartridge is then preferably moved back onto the reader tray and the reader tray is ejected leaving the cartridge external to the reader and ready for the user, or optionally an automated system, to remove the cartridge from the tray and dispose of it properly.

[0286] A preferred embodiment of the performance of an assay using cartridge 3200 is described below, the description focusing on aspects that differ from the operational steps described for cartridge 2500. The operational description includes the use of a preferred valve configuration in the cartridge reader that is similar to that described in FIG. 24 except that it is configured so that air vent port 3244 and air bubble trap vent port 3266 can be connected to the pump, sealed or vented to the atmosphere. In view of the operational description provided for cartridge 2500, the basic operations that are used to move fluid in this preferred embodiment (i.e., opening vent ports on one side of the fluid to be moved to air and applying positive or negative pressure to a vent port on the other side of the liquid) will be apparent and are not always described.

[0287] A sample, preferably a sample comprising and/or collected on a solid matrix, is inserted in sample chamber 3220 and cap 3297 is closed. In an especially preferred embodiment, the sample (most preferably an upper respiratory sample and/or a sample suspected of containing a

streptococcus strain) was collected on an applicator stick (preferably a swab), the applicator stick preferably comprises a pre-defined weak point and the sample chamber is curved as shown in FIG. 33. In this especially preferred embodiment, insertion of the stick into the curved chamber causes the shaft to break. The shaft segment is then, preferably, removed and the head segment is sealed in the chamber by closing cap 3297.

[0288] The cartridge is inserted into a reader and mated to the appropriate electrical and fluidic connections as described above for cartridge 2500. The cartridge preferably holds ampoules of extraction and wash buffer in, respectively, reagent chambers 3210 and 3240 which are preferably broken now (or alternatively any time before they are required). The extraction reagent (preferably, nitrous acid, more preferably, nitrous acid made from a liquid acid in a reagent ampoule and a dry nitrate salt present outside the ampoule in chamber 3210) is pulled from its reagent chamber 3210 by opening vent port 3212 to air, vent port 3244 or 3264 to the pump, and operating the pump to draw the extraction reagent through the swab. To eliminate bubbles in the sample, the pump is operated until fluid from the swab is detected at sensor position #1. The fluid is then pushed into bubble trap 3226 by opening vent port 3266 to air and operating the pump to apply positive pressure at vent port 3244 or 3264 (or the reverse, i.e., applying negative pressure at vent port 3266 and opening vent port 3244 or 3264 to air). In bubble trap 3226, the bubbles rise to the top of the trap leaving bubble free liquid at the bottom of the trap. More fluid from the swab is pulled up to sensor #1 and again pushed into the bubble trap. This is repeated as often as necessary to ensure enough bubble-free liquid is collected in the bubble trap to conduct the assay.

[0289] Bubble-free sample liquid is then drawn from the bottom of bubble trap 3226 (by aspirating from vent port 3244 or 3264 with vent port 3266 open to air) until the fluid front reaches sensor #1. Vent port 3266 is closed and vent port 3262 is opened to air and the defined slug of sample is drawn forward, pulling air behind it from vent port 3262. This process accurately measures out a defined volume of sample liquid. The sample slug is then drawn across dry assay reagent 3225 to dissolve it—this reagent preferably includes buffers, labeled binding reagents (preferably antibodies) for the assays, stabilizing reagents, and/or other additives such as blocking reagents. For assays employing nitrous acid as an extraction reagent, the dry assay reagent preferably comprises sufficient base (preferably, the base form a pH buffer such as Tris, Hepes, phosphate, PIPES, etc.) to bring the pH of the sample to between 4-10, more preferably between 5-9, more preferably between 6-8. The dissolved reagents may be mixed into the sample by moving the sample back and forth in the fluid line, using sensors to ensure that the liquid remains within a defined region of conduit.

[0290] The sample containing the reconstituted assay reagents is then drawn into detection chamber 3230, where immobilized binding agents (preferably antibodies) are present on individual binding zones that are, more preferably, located on electrodes in an electrode array. The sample is incubated for a specific time period over the binding zones, either in a static mode or under mixing, during which time the analyte and labeled binding reagent can bind to each other and/or to the individual binding zones. Mixing is